Turbi Quick

USER'S MANUAL

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INSTRUMENT NAME: **Turbi-Quick®**

INSTRUMENT MANUFACTURER: **Vital Diagnostics S.r.l.**
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INSTRUMENT DISTRIBUTOR:

Please read this manual completely before using the instrument

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1. INTRODUCTION

Dear User, we hope you will be satisfied with your Turbi-Quick® analyzer.
The Turbi-Quick® analyzer is a reader especially developed for coagulation and immunochemistry analyses.
The coagulation tests are performed using the optical detection of the clot: once the clot is formed, there is an absorbance shift which allows the detection of the end of the reaction.
For what concerns instead Immunochemistry, a complete panel of quantitative immunoturbidimetric analyses is available for the Turbi-Quick® reader: all the tests have been studied by Vital Diagnostics and optimized for the Turbi Quick® reader. All the tests are based on the Turbidimetry principle: the attenuation of the intensity of the light through a solution containing Antigen-Antibody aggregates, is proportional to the Antigen concentration.

This manual describes the Turbi-Quick® way of working. Please read it completely to understand the capabilities of your instrument.

1.1 INTENDED USE

The Turbi Quick analyzer is a semi-automated photometer developed for the analysis of coagulation and immunochemistry parameters, performed on human serum or plasma. The complete list of tests available on the instrument, is supplied and updated only by Vital Diagnostics S.r.l. and supplied together with the instrument.

1.2 IMPROPER USE

Following uses are considered improper:
1) The use of the device by not qualified personnel
2) The use of cuvettes different from those specified on the manual and on the inserts
3) The cuvette re-use
4) The use of reagents different from those specified on the the manual and on the inserts
5) Every attempt to analyze samples different from human serum or plasma
6) Every attempt to obtain different parameters form those specified on the inserts
7) The exposure of the device and of the optical part to liquids, which can soak into the reading system.
8) The insertion of devices different form cuvettes into the reading channel
9) Disregard instructions given on this manual

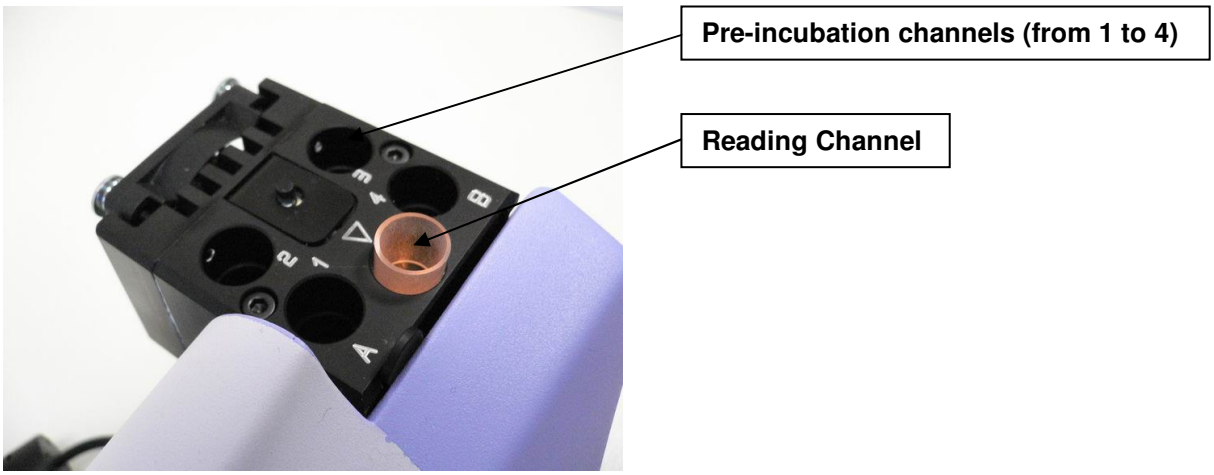
The above mentioned uses and every attempt to use the Turbi Quick with a purpose different from the intended use, must be considered improper.

2. INSTRUMENT DESCRIPTION

2.1 CUVETTES HOLDER

In the upper part of the Turbi-Quick reader, there is the cuvettes holder: that is automatically thermostatized at 37°C. It has with 5 channels. Channel from 1 to 4 are pre-incubation channels and can be used to reach the sample's temperature of 37°C.
The channel marked with "∇" is instead the reading channel where cuvettes must be transferred after the pre-incubation phase.

The reading channel is a photometer with two different filters (A and B) available.



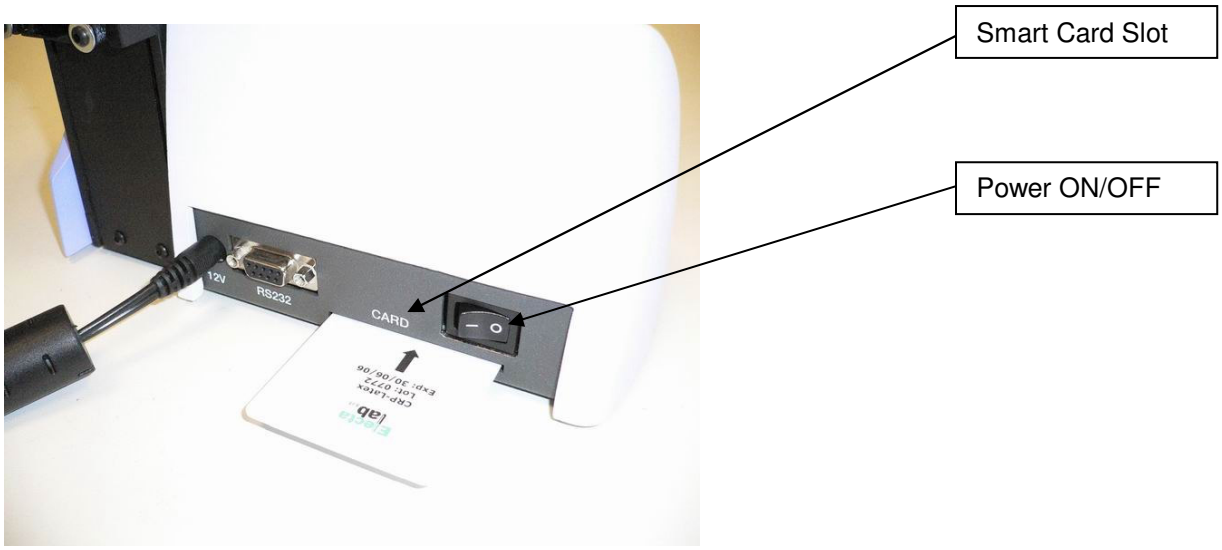
2.2 SMART CARD

The Turbi-Quick® reader works only in association with Turbi-kits®. Turbi-kits® are the reagents needed to perform analyses on the instrument and inside each Turbi-kit box, there is a Smart Card. The smart card must be inserted in the Smart Card Slot, located in the rear panel of the instrument. Without the smart card, the instrument doesn't work.

Smart Card

In the Smart Card's chip in fact, the following data are stored:

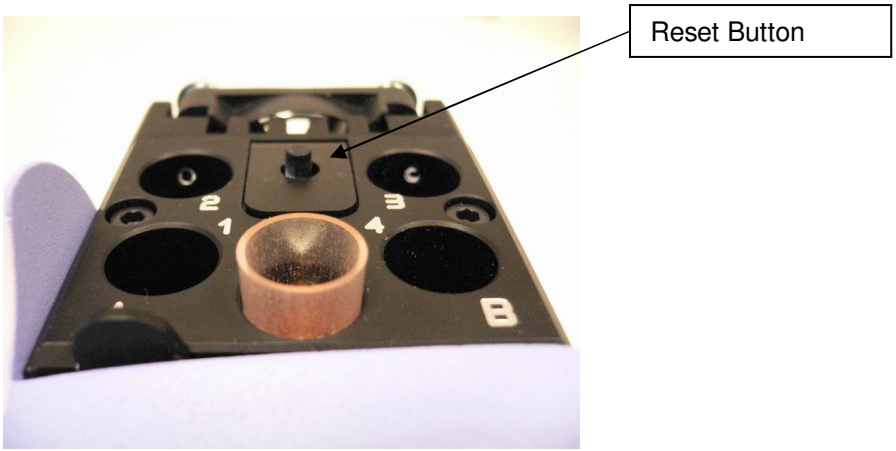
- Calibration Curve: in each card the calibration curve of the test is stored: in this way the Operator doesn't need to perform the calibration curve, but he can start immediately with patient's samples.
- Test Settings: reading time, mixer behavior and kind of filter are already stored in the card in order to avoid incorrect readings due to wrong filter, mixing or reading time setting errors.
- Expiry Date: the Expiry Date of the kit is stored on the card in order to avoid the use of expired kits.
- Number of test: the number of tests performable with the kit, is stored in the card: this counter will decrease each time the user performs one test.



Smart Card Slot and Power ON/OFF switch

2.3 RESET BUTTON

On the upper part of the cuvettes holder, between channel 2 and 3, is located the Reset Button which can be used to reset the instrument. The complete functioning of this button is explained in this manual. Please read it carefully before use the Turbi-Quick®.



2.4 FILTERS SELECTOR

On the front side of the cuvettes holder, just in front of the reading channel, is located the Filters Selector. This selector allows the user selecting between 2 different filters: filter A and filter B.
Each test, requires a specific filter: the filter needed, appears on the Turbi-Quick's display as soon as the instrument, with a Smart Card inserted into the slot, is switched on.
To change the filter, move the lever to the left for filter A or to the right for filter B.
The filter should be selected before switching on the instrument. The filter required is also written in the internal insert of each kit.

3. INSTALLATION

3.1 TURBI-QUICK POSITIONING

The Turbi-Quick® shouldn't be placed near centrifuges, oscillating agitators or other vibrating instruments that might cause movement of the bench.
It should be placed far from windows or direct light sources to avoid Turbi-Quick® overheating.

3.2 POWER ON

Connect power supply outlet to the instrument.
Insert the power supply plug in a socket with an earth connection.
If the instrument has an optional printer, it should be connected to the Turbi-Quick® with the appropriate cable and plugged in.
Insert the Smart Card in the slot. Select the Filter. Switch on the instrument.
Once the Turbi-Quick® is switched on, on the display you can see:

```
+------------------+
|   Turbi-Quick    |
|   Reader V.X.X   |
+------------------+
```

If the printer is connected to the instrument, the same information will be also printed out.
If the Smart Card is not recognized by the instrument, or is not inserted in the slot, on the display will appear:

```
+------------------+
| Invalid card,    |
| turn off and     |
| replace the card |
+------------------+
```

In this case, the instrument must be switched off, the Smart Card changed or inserted into the slot, and then the instrument can be switched on again.
Now, on the display will appear this message:

```
XX         Filter: A

Lot.9999   16/05/05
test counter: 9999
```

and, if the printer is connected, the following information will be also printed out:

```
Analysis : XX
Filter   : A
Lot.nr.  : 9999
Exp.date : 16/05/05
T.counter: 9999
```

Where: First Line: Name of the test
Second Line: Filter required
Third Line: Kit's lot number
Fourth Line: Kit's expiry date
Fifth Line: Test counter. This counter will decrease each time the user performs one test.

If the test counter is zero, on the display will appear:

```
+------------------+
|test counter = 0  |
|turn off,         |
|and replace card..|
```

This message will appear when the maximum number of test per kit have been achieved and kits reagents are finished.
Once will appear this message, switch off the instrument, open a new kit and insert into the slot, the new Smart Card. Now you can switch on again the Turbi-Quick®.

3.3 WARM UP AND CALIBRATION

Once the instrument is switched on with a correct Smart Card, it will start the warm-up procedure: during this time, the Turbi-Quick® will heat the cuvette holder until the temperature of 37°C is reached.
On the display will appear:

```
+------------------+
|Warmup to 37.0 C. |
|Temperature: 34.6 |
+------------------+
```

Once 37°C are reached, the Turbi-Quick® will perform the auto calibration and the filter checking.
On the display will appear:

```
+------------------+
|Filter calibration|
|  please wait...  |
+------------------+
```

If some calibration problems occur, on the display will appear:

```
+--Reading error!--+
|Check r. channel  |
|Check filter pos. |
|and press button  |
```

This message can be displayed when:
The filter selected is wrong: in this case, move the filter's selector to the other filter and press the Reset Button. The Turbi-Quick® will repeat again the calibration with the right filter.
The reading channel is not empty: in this case, remove the cuvette from the reading channel and then press the Reset Button. The Turbi-Quick® will repeat the calibration.

3.4 LAMP WARMING UP PROCESS

Once the calibration is finished, the Turbi-Quick® reader starts the Lamp warming up process and on the display will appear:

```
+------------------+
| Lamp warmup      |
| please wait...   |
+------------------+
```

During this phase, the lamp reaches the correct operating temperature. Once this process has been completed, the instrument is ready to work.
To know how to proceed, see the Operating Procedures of this manual.

4. OPERATING RECOMMENDATIONS

These recommendations are essential to work correctly with Turbi-Quick® reader and with Turbi-Kits. Please, before performing analyses, read carefully these recommendations.

1. Once the cuvette has been inserted into the Reading Channel, don't touch the cuvette until the reading time is finished: the cuvette's movement could cause an erroneous sample's reading.

2. Once the cuvette has been inserted into the Reading Channel, don't remove the cuvette until the reading time is finished: the cuvette's removing causes an erroneous reading process.

3. To obtain reproducible results with Turbi-Quick® reader, it is necessary to use calibrated pipettes: an erroneous volume of reagents will cause an incorrect ratio between reagents and consequently results won't be reproducible. Vital Diagnostics recommends to calibrate pipettes at least every six months.

4. The Smart Card can be removed from the Turbi-Quick® only when the reader is switched off or is in stand-by mode. Removing the Smart Card while the instrument is working can damage Turbi-Quick® and cause an erroneous sample's reading.

5. During the injection of the Starter reagent, avoid bubble formation. Bubbles can create interference with the light source and cause an erroneous reading. In case of bubbles, we suggest to prepare a new sample.

6. Inject the Starter reagent, straight on the light bundle. Do not insert the whole pipette tip into the cuvette, but just the end of the tip.

7. When insert the cuvette into the Reading channel, push it down strongly, until the cuvette reaches the bottom of the channel. This operation is very important, because an incorrect cuvette positioning will cause an erroneous sample's reading.

8. Each sample and/or control must be prepared following the instruction sheet inside each Turbi Kit. Once the sample is ready, transfer the cuvette into channels 1 – 4 for the pre-incubation. Maintain the cuvette into the pre-incubation channel for the time shown on the instruction sheet. Once the pre-incubation time is finished, transfer the cuvette into the reading channel and follow all the indication previously described to perform the test.

5. SAFETY MEASURES

5.1 USER PRECAUTIONS

Before using the analyzer, the operator must know the rules for handling potentially infectious materials and electro-mechanical systems.

5.2 ELECTRICAL EQUIPMENT

As with all electrical equipment, the power supply is a potential source of danger. To prevent the risk of electrical shock to the user and/or damage the instrument, the operator should not open any part (electrical) of the instrument. Only authorized personnel, such as service technicians, may open the instrument to perform maintenance or repair.

5.3 SAMPLES

All biological fluids must be considered by the operator as potentially infectious. For this reason, the operator must adopt the national and international standards of precautions to avoid the biological danger.
Specimens (patient samples and controls) and liquid waste should be considered potentially infectious and capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV) and other

blood borne pathogens.
The handling of these substances must be performed in accordance with established laboratory safety regulations in order to minimize risk for laboratory staff.
This includes wearing of gloves, splash protection, etc. Contact with skin and mucous membranes must be avoided. This also applies to all components of the instrument that are exposed to these substances.
If any specimen is spilled on the instrument, wipe it up immediately and clean the contaminated surface with a disinfectant of 0.5% sodium hypochlorite solution.
Compliance with local regulations pertaining to the disposal of waste is the responsibility of the operator.
Refer to local sources for additional information on correct biohazardous waste disposal.
Qualified technical operators must apply the same warning procedures for instrument maintenance.

5.4 NOTES ON SAFETY MEASURES

On the instrument, to assure a correct use of the instrument, may be placed the following symbols:

Attention: read use instruction

For in vitro diagnostic use only

ELECTROSTATIC DISCHARGE SENSITIVE DEVICE (ESDS):
The device could be damaged by electrostatic potentials

5.5 RESIDUAL RISKS

Despite of the measures taken in the designing of the machine to guarantee a safe use of it, there might happen reasonably predictable occurrences, whose risk was possible to reduce, but not to eliminate completely.

RESIDUAL RISKS	PROTECTION MEASURES
Biological contamination	The operator must wear always gloves and protection glasses, as prescribed by laboratory regulations. Do not ever open tubes
Cuvettes breaking and/or overthrow	In case of cuvettes accidental broken and/or overthrow, clean the instrument with a sodium hypochlorite solution.
Cuvettes re-use	Cuvettes are disposable, so the re-use of cuvettes can false the analysis result

6. COAGULATION OPERATING PROCEDURE

When a Coagulation smart card is inserted in the Turbi Quick, follow these instructions.

6.1 FOREWORDS

The cuvettes required to perform coagulation test have a volume of 1.5 mL and a particular shape studied to reduce the volume of reagent needed (code: ACC16-047). Only this kind of cuvette is suitable to perform coagulation tests. All the cuvettes different from ACC16-047 must be discarded.
Coagulation tests are very sensible to the temperature. Strictly respect pre incubation time to obtain reproducible results.

6.2 CONTROL MODE

Few seconds after the warming up process of the lamp, the Turbi-Quick will automatically enter in the Control Mode and on the display a Control sample will be required: the instrument now is ready to analyze one or more Control:

```
PT
Control n. 1
insert cuvette..
and press button
```

When this indication **(Stand by mode)** appears on the display the Operator has to press rapidly the button. On the display will appear:

```
PT
Control n. 1
when T=0   add
PT Rea.      T=5"
```

A 5 seconds countdown will start: when the T = zero seconds, on the display will appear the following message:

```
PT
Control n. 1
add PT Rea...
```

Now the operator has 3 seconds to inject the starter reagent.
During these three seconds, on the display will appear:

```
PT
Control n. 1
mixing...
```

And immediately after:

```
PT
Control n. 1
Time: XX
```

Once the analysis is finished (the clot is formed), the timer stops, and on the display appears:

```
Control n. 1
PT =26.3   INR=2.43
PT%=222
Press the button...
```

If the a printer is connected, the same information will be also printed out.
Once the analysis is finished (the clot is formed), the timer stops, and on the display appears:

```
   Control n. 1
PT =26.3   INR=2.43
     PT%=222
Press the button...
```

If the a printer is connected, the same information will be also printed out.
Now the operator can:

a. Press the button rapidly (less than 2 seconds) In this case, the analyzer will enter in the stand by mode, and is ready for a new control:

```
          PT
   Control n. 2
insert cuvette..
and press button
```

b. Press the button more than 2 seconds If the operator wants to start to analyze patient's sample, he can press more than 2 second the button: the instrument will enter to Sample mode and on the display will appear:

```
          PT
   Sample n. 1
insert cuvette..
and press button
```

Now, follow instructions described at point 6.3.

6.3 SAMPLE MODE (PRESS THE BUTTON MORE THAN 2 SECONDS)

In case the operator does not want to perform any control, he can start immediately to analyze patient's samples. To pass directly to Sample mode, press the button for more than 2 seconds, then on the display will appear:

```
          PT
   Sample n. 1
insert cuvette..
and press button
```

When this indication (Stand by mode) appears on the display the Operator must insert the cuvette into the reading channel and then press rapidly (less than 2 seconds) the button. In this way a 5 seconds countdown will start: when the T = zero seconds, on the display will appear the following message:

```
          PT
   Sample n. 1

add PT Rea...
```

Now the operator has 3 seconds to inject the starter reagent.
During these three seconds, on the display will appear:

```
          PT
   Sample n. 1

    mixing...
```

And immediately after:

```
          PT
   Sample n. 1

    Time: XX
```

Once the analysis is finished (the clot is formed), the timer stops, and on the display appears:

```
    Sample n. 1
PT =26.3   INR=2.43
     PT%=222
Press the button...
```

If the a printer is connected, the same information will be also printed out.
Now the operator should press the button rapidly (less than 2 seconds): in this way the analyzer will enter in the stand by mode, and is ready for a new sample:

```
        PT
   Sample n. 2
insert cuvette..
and press button
```

6.4 READING ERROR MESSAGE

In some particular tests like PT or APTT, can happen that the clot doesn't form, so the instrument can't fix the end of the reaction. When this happens, the following message will appear on the display:

```
        PT
   Sample n.1
 Reading error
Press the button
```

In this case, remove the cuvette from the reading channel and press the button rapidly (less than 2 sec): in this way the instrument will return in the stand-by mode:

```
        PT
   Sample n. 2
insert cuvette..
and press button
```

7. IMMUNOTURBIDIMETRIC OPERATING PROCEDURE

When an Immunoturbidimetric smart card is inserted in the Turbi Quick, follow these instructions.

7.1 CONTROL MODE

Few seconds after the warming up process of the lamp, the Turbi-Quick® will automatically enter in the Control Mode and on the display a Control sample will be required: the instrument now is ready to analyze one or more Control:

```
    CRP-Latex
  Control n. 1
insert cuvette..
and press button
```

The operator now has to press rapidly the button, on the display will appear:

```
    CRP-Latex
  Control n. 1
 when T=0   add
sample       T=5"
```

A 5 seconds countdown will start: when the T = zero seconds, on the display will appear the following message:

```
CRP-Latex
Control n. 1
add sample...
```

Now the operator has 3 seconds to inject the starter reagent. Once the sample has been injected, on the display will appear:

```
CRP-Latex
Control n. 1
mixing...
```

And immediately after:

```
CRP-Latex
Control n. 1
reading...
```

```
CRP-Latex
Control n. 1
Time: 119"
```

Once the reading time has expired, on the display will appear:

```
CRP-Latex
Control n. 1
conc. 12.3 mg/L
press the button...
```

If the a printer is connected, the same information will be also printed out.
Now the operator can:

a. press the button more than 2 seconds

If the operator wants to start to analyze patient's sample (and not controls), he can press more than 2 second the button: the instrument will enter to Sample mode and on the display will appear:

```
CRP-Latex
Sample n. 1
insert cuvette..
```

Now follow instructions described at point 7.2.

b. press the button rapidly (less than 2 seconds)

In this case, the analyzer will enter in the stand-by mode, and is ready for a new control:

```
CRP-Latex
Control n. 2
insert cuvette..
and press button
```

Now the operator can run another control as previously described

7.2 SAMPLE MODE (PRESS THE BUTTON MORE THAN 2 SECONDS)

In case the operator does not want to perform any control, he can start immediately to analyze patient's samples. To pass directly to Sample mode, press the button for more than 2 seconds while the instrument is in stand by mode, then on the display will appear:

```
CRP-Latex
Sample n. 1
insert cuvette..
and press button
```

When this indication (Stand by mode) appears on the display the Operator must insert the cuvette into the reading channel and then press rapidly (less than 2 seconds) the button. In this way a 5 seconds countdown will start: when the T = zero seconds, on the display will appear the following message:

```
CRP-Latex
Sample n. 1

add sample...
```

Now the operator has 3 seconds to inject the starter reagent. During these three seconds, on the display will appear:

```
CRP-Latex
Sample n. 1
mixing...
```

And immediately after:

```
CRP-Latex
Sample n. 1
reading...

CRP-Latex
Sample n. 1
Time: 119"
```

Once the reading time has expired, on the display will appear:

```
CRP-Latex
Sample n. 1
conc. 12.3 mg/L
press the button...
```

If the a printer is connected, the same information will be also printed out. Now the operator should press the button rapidly (less than 2 seconds): in this way the analyzer will enter in the stand by mode, and is ready for a new sample

```
CRP-Latex
Sample n. 2
insert cuvette..
and press button
```

8. TROUBLESHOOTING

8.1 THE INSTRUMENT DOESN'T RECOGNIZE THE STARTER INJECTION

In case the injection time has been expired, and the reagent has not been injected, on the display will appear:

```
PT
Control n. 1
PT Rea. not detected
repeat sample...
```

In this case, press the button rapidly (less than 2 sec.): on the display will appear:

```
PT
Control n. 1
insert cuvette..
and press button
```

Now the instrument is ready again to perform the test, press again the button and insert the starter reagent when the display requires the injection.

In case the reagent has been injected, due to the small reagent volume and/or the small reagent absorbance, the analyzer can't recognize the injection. the operator has to press the button within 2 seconds and on the display will appear consequently:

```
CRP-Latex
Control n. 1
mixing...
```

```
CRP-Latex
Control n. 1
reading...
```

```
CRP-Latex
Control n. 1
Time: 119"
```

Once the reading time has expired, on the display will appear:

```
CRP-Latex
Control n. 1
conc. 12.3 mg/L
press the button...
```

If the a printer is connected, the same information will be also printed out.
Now the operator can run another sample as previously described

8.2 SMART CARD CHANGE

It is possible to change the smart card, also without switching off the instrument. This special feature is available only during the analyzer stand-by mode. The stand-by mode can be displayed both during samples analyses and during controls analyses:

A) during control mode
The stand-by mode is displayed as follows:

```
PT
Control n. 1
insert cuvette..
and press button
```

Under this condition, to change the smart card, it is necessary firstly to pass from control to sample mode: pressing the button for more than 2 seconds, the analyzer will enter in the sample mode:

```
PT
Sample n. 1
insert cuvette..
and press button
```

Now it is possible to remove the smart card and insert a new one and pass from, e.g., PT analysis to APTT analysis. To do that, follow the instructions described under point B).

B) during sample mode
The stand-by mode is displayed as follows:

```
PT
Sample n. 1
insert cuvette..
and press button
```

Under this condition, it is possible to remove the smart card and insert a new one and pass from, e.g., PT analysis to APTT analysis.
To do that, remove the old smart card and insert the new one. Then press more than 2 seconds the button, so the instrument will start again with the calibration procedure:

```
+------------------+
|   Turbi-Quick    |
|   Reader V.X.X   |
+------------------+

APTT      Filter: A

Lot.9999   16/05/05
test counter:  9999

 +------------------+
 | Warmup to 37.0 C.|
 |Temperature: 34.6 |
 +------------------+


+------------------+
|Filter calibration|
|  please wait...  |
+------------------+

        APTT
   Control n. 1
 insert cuvette..
 and press button
```

Now the instrument is in Control Mode, ready to analyze the first APTT control.

8.3 HIGH/LOW SAMPLE'S CONCENTRATION

For those analytes expressed in concentration (e.g. Fibrinogen), if a sample has a concentration lower than the minimum value of the linear range, on the display will appear:

```
Fibrinogen
Sample n. 1
conc.<10.0 mg/L
press the button...
```

While if a sample has concentration higher than the maximum value of the linear range, on the display will appear:

```
Fibrinogen
Sample n. 1
conc.>300 mg/L
press the button...
```

In this case, the operator can repeat the test after sample's dilution (follow insert instructions)

8.4 READING ERRORS

In case of reading errors, the following messages can appear:

```
+--Reading error!--+
|Check r. channel  |
|Check filter pos. |
|and press button  |
```

In this case the operator can:
a – check if the filter selected is the right one: if not, move the filter lever on the right position, and press the button. The instrument will check the reading system again.
b – check if the reading channel is empty. In case the reading channel is not empty, remove the cuvette and press the button
If these 2 operations, won't solve the problem, call the technical assistance.

```
+---White error!---+
|Check r. channel  |
|and press button  |
+------------------+
```

In this case the operator can:
a – check if the filter selected is the right one: if not, move the filter lever on the right position, and press the button. The instrument will check the reading system again.
b – change the lamp as described on this manual.
If these 2 operations, won't solve the problem, call the technical assistance.

```
+---Black error!---+
|Check r. channel  |
|and press button  |
+------------------+
```

In this case the operator can:
a – check if there is a direct source of light on the instrument. Remove the direct source of light from the instrument
If this operation, won't solve the problem, call the technical assistance.

9. MAINTENANCE

Its simplicity and component parts mean that the Turbi Quick does not require special maintenance. The most sensitive part is the lamp which can be easily replaced in case of damage (see further). Care and attention are required above all regarding the cleanliness of the upper part (reading part) which must be kept dry and clean. The soaking of the upper part, can damage the reading system. Do not clean the upper plate with liquids or damp cloths.

9.1 CLEANING INSTRUCTIONS

Dust can be removed using an ordinary vacuum cleaner. In case of cuvettes accidental broken and/or overthrow, clean the instrument with a sodium hypochlorite solution.

9.2 LAMP REPLACEMENT

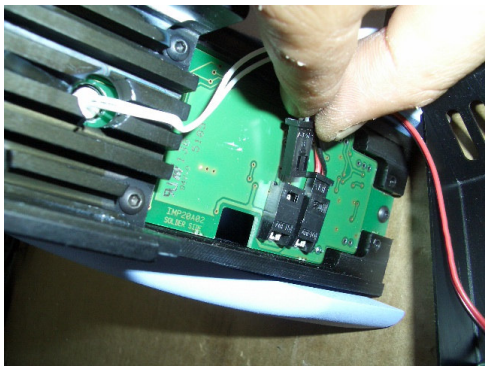
In each Turbi Quick package, is inserted a lamp as spare part.
In case of blown lamp, follow these instructions to replace the lamp.

Picture 1

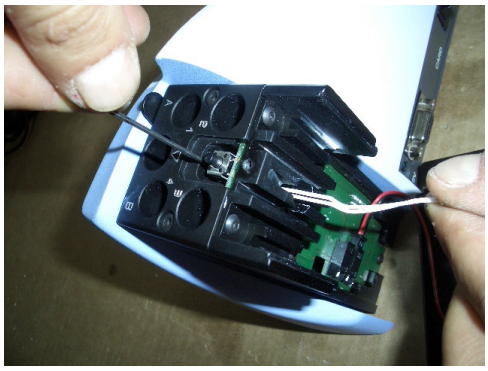
Picture 2

Picture 3

Unscrew the 3 screw as shown in pictures 1 and 2, then remove the back panel of the photometer as shown in picture 3.
Now disconnect the cable of the lamp (white cable) as shown in picture 4.



Picture 4



Picture 5

Unscrew the screw blocks the lamp as shown in picture 5 and then remove the lamp.
Insert a new lamp, block it whit the screw, connect the cable and mount the back panel of the photometer.

10. PERFORMANCE CRITERIA AND LIMITATIONS

10.1 PERFORMANCE CRITERIA

A. Optical detection precision	:	0.001 O.D. (Photometric Measurement)
B. Analysis Reproducibility	:	C.V. % < 6 (test depending)
C. Cuvette Holder block thermostatized 37°C	:	Automatic (room temperature between 15-32 °C)
D. Photometric zeroing	:	Automatic
E. measuring points	:	2
F. Measuring range	:	0 – 1.5 O.D.

10.2 LIMITATIONS

A. Strongly lipemic or haemolytic samples may alter instrument's reading capability.

B. Samples with a concentration > or < than linear range.

11. TECHNICAL SPECIFICATIONS

Area of application	:	Immunochemistry and coagulation analyses
Instrument size	:	Height 145 mm Width 210 mm Depth 120 mm
Weight	:	1100 gr.
Voltage	:	external power supply 240 V (110 V) A.C. 50 (60) Hz output +12 V dc 3.5 A
Reading Channel	:	1
Pre-incubation Channels	:	4
Thermostatization	:	37 °C
Analysis time	:	kit's dependent
Loading pattern	:	One test a time
Results	:	Shown on the display and printed out (if a printer is connected) Expressed in concentration
Measuring Principle	:	Photometric
Filters	:	Filter A (near UV) Filter B (UV)
Reading resolution	:	+/- 0.001 O.D.
Display interface	:	LCD 20 x 4 with back-light
Interface	:	RS 232 for printer
Software	:	Integrated
CE Marked	:	yes

12. EC DECLARATION

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE Dispositivi Medico-Diagnostici In Vitro
conforme all'Allegato II della Direttiva 2006/42/CE Direttiva Macchine
according to Annex III of the Directive 98/79/CE In Vitro Diagnostic Medical Devices
according to Annex II of the Directive 2006/42/CE

fabbricante *manufacturer*	**Vital Diagnostics S.r.l.**
indirizzo *address*	Via Balzella 41/G/4 47100 FORLI' ITALIA
telefono 0039 0543 721220 *phone*	fax 0039 0543 796001 *fax*
Identificazione dei prodotti *Product identification*	**Lettore per analisi immunochimiche effettuate con metodo turbidimetrico** ***Reader for immunochemistry analyses performed by turbidimetric method***
Nome commerciale *Brand name*	**TURBI QUICK**
Numero/i di catalogo *Part number/s*	**PRD-IMP-XXX**
classificazione dei prodotti *product identification*	dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE *devices other then those mentioned in Annex II of the Directive 98/79/EC*

Si dichiara sotto la propria responsabilità che
i dispositivi sopraelencati rispettano le disposizioni applicabili delle seguenti direttive:

Hereby we declare under our sole responsibility that
the above mentioned devices meet the applicable provisions of the following Directives:

Direttiva 98/79/CE
Direttiva 2006/42/CE
Direttiva 2004/108/CE (Compatibilità Elettromagnetica)
Direttiva 2006/95/CE (Bassa Tensione)
Direttiva 2002/96/CE e 2003/108/CE (RAEE)
Direttiva 2002/95/CE (RoHs)

Tutta la documentazione tecnica comprovante il rispetto dei requisiti applicabili delle Direttive elencate, è conservata a cura del Fabbricante

All the technical documents required to demonstrate the conformity to the listed Directives, are kept by the Manufacturer

luogo e data *place and date*	Forlì, 10/03/2008	anno di immissione in commercio *year of introduction on the market*	2005
firma *signature*			
timbro della Società			

13. DISPOSAL AND RECYCLING

Herewith we declare that this instrument is subject to the European Directive 2002/96/EC (RAEE Directive). Therefore the instrument must be disposed separately, not as urban waste and delivered to the specific collection center in according to the Directive 2002/96/EC.
The user can ask to the dealer the collection of the instrument if a new instrument is ordered to replace the old one. On the instrument there is a label with the symbol shown in this page. The symbol means that the instrument cannot be disposed as urban waste.